REMARKS

The specification has been amended to provide the chemical names for some trademarked products. Support is found in the attached website materials for Docetaxel, Bronopol, and VANTOCIL (Attachment A). These materials can be found at the following URLs:

http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a696031.html;

http://www.chemindustry.com/chemicals/search/B/bronopol.html;

http://www.archbiocides.com/newproducts/vantocil/default.asp.

Claims 33-34 have likewise been amended to refer to the chemical names. Typographical errors have been corrected.

Claims 56-60 have been added; these claims include no new matter. The shape of the scaffold is discussed, for example, at page 7, lines 5-7 and 14-15. The therapeutic agents are discussed, for example, at page 14, lines 4-17. Based on the present Amendment and the following Remarks, Applicants respectfully request that the Examiner reconsider and withdraw all outstanding rejections.

Claims 61-68 have been added; these claims include no new matter. Support regarding the coated scaffold may be found, for example, on pages 12-16 of the written description. Support regarding the therapeutic agent may be found, for example, at page 6, lines 9-13; page 12, lines 1-5; page 14, lines 4-6 and 11-17; page 15, line 11; page 16, line 1; page 20, the table following line 15; and page 21, lines 1-4. A metal scaffold is discussed, for example, at the following: page 7, lines 14-15 and 29-33; page 9, lines 20-23; page 10, lines 24-27; page 16, line 1; and page 21, lines 14-15. Loading of the therapeutic agent is discussed, for example, at page 5, lines 8-12.

Claims 25-42 have been amended to depend from claim 61, rather than from claim 23. Thus, the limitation of a loading of at least 100 micrograms per square centimeter of coating has been removed, and the limitation of the therapeutic agent comprising an antithrombogenic and/or an antiangiogenic agent in an effective amount has been added to claims 25-42. Claims 43, 45, and 50 have been amended to remove the limitation of a loading of therapeutic agent of at least about 100 micrograms per square centimeter, and dependent claims 69-71 including the limitation of a loading

of therapeutic agent of at least about 100 micrograms per square centimeter have been added.

Rejections under 35 U.S.C. § 103 over U.S. Patent No. 6,110,483 to Whitbourne et al.

Claims 23-25 and 28-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,110,483 to Whitbourne et al. (hereinafter '483), as indicated in item 3 on page 2 of the Office action of January 6, 2005.

The examiner concedes that '483 is "silent to the specific design of the substrates regarding their edges and surfaces" (Office action, item 4, page 3). Independent claim 23 of the instant application requires that "a scaffold compris[e] adjacent edges or surfaces in close proximity to each other". Because '483 does not teach the location and orientation of edges and surfaces, it does not teach or suggest the limitation of claim 23 of a scaffold comprising adjacent edges or surfaces in close proximity to each other.

Independent claim 23 of the instant application further recites "said coating ... bridging from one edge or surface to another..." In the written description of the instant application, an example is provided of a device in which the scaffold is a coil having open windings, with the coating "not only cover[ing] the surface of the wire, but also bridg[ing] from one winding to the next..." (instant application, page 7, lines 17-18). '483 does not teach the limitation of independent claim 23 of the instant application of bridging of the coating, but rather only teaches that the coating "forms a thin continuous layer over the substrate..." ('483, column 3, lines 17-18).

Claims 43, 45, and 50 similarly refer to "edges or surfaces in close proximity to each other..." and a formulation or coating bridging from one edge or surface to another. Thus, the '483 patent does not teach or suggest all the claim limitations of the independent claims 23, 43, 45, and 50, and thus does not teach or suggest all the limitations of the dependent claims. The examiner has not established a *prima facie* case of obviousness. In rejecting independent claims 23, 43, 45, and 50, and claims which depend from them, the examiner does not identify a suggestion or motivation found in the '483 patent to modify the teachings of '483. Applicants therefore respectfully request that the rejection of independent claims 23, 43, 45, and 50, and of dependent claims 24-25, 28-42,

44, 46-49, and 51-55 under 35 U.S.C. 103(a) over U.S. Patent No. 6,110,483 to Whitbourne et al. be withdrawn.

With respect to claims 41 and 42, the examiner states that "[i]t would be well within the limits of ordinary skill in the art to determine the optimal component ranges operation for the polymer coating giving the general conditions of the specification." As presented in the July 15, 2005 Amendment, Table V of the written description illustrates that the release rate characteristics of a polymer formulation are dependent on the proportion of hydrophilic to hydrophobic polymer. Moreover, a device coated with the particular polymers and polymer blends, such as a blend of hydrophobic and hydrophilic polymers as claimed in claims 36-42 of the instant application is not a routine variant, and thus would not be obvious to one of ordinary skill in the art.

Rejections under 35 U.S.C. § 103 over U.S. Patent No. 6,110,483 to Whitbourne et al. and U.S. Patent No. 6,335,029 to Kamath et al.

Claims 26-27 and 53-55 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the combined disclosures of U.S. Patent No. 6,110,483 to Whitbourne et al. and U.S. Patent No. 6,335,029 to Kamath et al. (hereinafter '029), as indicated in item 8 on page 4 of the Office action of January 6, 2005. The examiner maintains that the '029 patent teaches a coil structure for a medical device, and that "[a] skilled artisan would have been motivated to continuously coat the coil as taught by '483". However, neither the '029 nor the '483 patent teaches a coating bridging between surfaces. Thus, the combination of the '029 and the '483 patents does not teach the limitations of independent claims 23, 43, 45, 50 or their dependent claims regarding "said coating ... bridging from one edge or surface to another...". Accordingly, the rejection of the dependent claims 26-27 and 53-55 cannot stand. Further, the examiner does not identify any suggestion or motivation in the '029 or the '483 patent to combine them or to modify their teachings to teach a device in which a coating bridges from one adjacent edge or surface to another.

In addition, '029 teaches the gas plasma deposition of a polymer barrier layer onto a medical device. The energy associated with gas plasma treatment could act to disrupt the structure of a

coating that bridges. Thus, '029 teaches away from independent claims 23, 43, 45, and 50 of the present invention, and teaches away from the dependent claims.

Applicants therefore respectfully request that the rejection of the claims 26-27 and 53-55 under 35 U.S.C. 103(a) over U.S. Patent No. 6,110,483 to Whitbourne et al. and U.S. Patent No. 6,335,029 to Kamath et al. be withdrawn.

Furthermore, there are additional reasons why several dependent claims are patentable. For example, neither the '438 nor the '029 patent teaches the limitation of claim 56, newly presented in this Amendment, that the scaffold has "a shape selected from the group consisting of mandrels, beads, egg-shapes, spheres, and threads".

Neither the '438 nor the '029 patent mentions the range of diffusion achieved by the medicated device. For example, these patents neither teach the limitation of claim 30 of the instant application that "when said device is implanted in a tissue, a therapeutic amount of said therapeutic agent diffuses at least about one centimeter from said device", nor the limitation of claim 31 that "in a zone of inhibition test, effective amounts of the therapeutic agent diffuse at least about one half centimeter from said device", nor the limitation of claim 45 that "a therapeutic amount of said therapeutic agent diffuses into the tissue at least about one centimeter from said device". The prior art devices and coatings do not teach such characteristics.

Also, neither reference teaches the classes of therapeutic agent mentioned in claims 57-58 or the therapeutic agents mentioned in claims 59-60. In summary, at least claims 30-31, 45, and 56-60 are patentable for additional reasons beyond those applicable to the independent claim from which they depend. Because of the reasons presented above, claims 23-60 are all patentable over U.S. Patent No. 6,110,483 to Whitbourne et al. and over the combination of '483 and U.S. Patent No. 6,335,029 to Kamath et al.

All of the stated grounds of rejection have been rendered moot. Applicants therefore respectfully request that the examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office action and, as such, the present application is in condition for allowance.

If the examiner believes, for any reason, that personal communication will expedite prosecution of this application, the examiner is hereby invited to telephone the undersigned at the number provided.

A Notice of Allowance for claims 23-60 is respectfully requested.

Respectfully submitted,

Date: July 1, 2005

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DC2/620762v8

Docetaxel

Printer-friendly version E-mail to a friend

(doe se tax' el)

Brand name(s): Taxotere

Contents of this page:

IMPORTANT WARNING:

Docetaxel can cause a decrease in the number of blood cells in your bone marrow. Docetaxel also can cause liver damage. Tell your doctor if you have or have ever had liver disease. Your doctor will order certain lab tests to check your response to docetaxel.Allergic reactions may occur during docetaxel administration; you will receive medication before each treatment to help prevent these reactions. With these preventive medications, these allergic reactions are uncommon. Your health care provider will watch you carefully during the initial part of the infusion to treat these effects if they occur. If you experience any of the following symptoms, call your doctor immediately: shortness of breath, facial flushing, fever, chest pain, dizziness, lightheadedness, or skin rash.

About your treatment

Your doctor has ordered the drug docetaxel to help treat your illness. The drug is given by injection into your vein.

This medication is used to treat:

- metastatic breast cancer

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

Docetaxel is in a class of drugs known as taxanes; it slows or stops the growth of cancer cells in your body. The length of treatment depends on the types of drugs you are taking, how well your body responds to them, and the type of cancer you have.

Precautions

Before taking docetaxel,

- tell your doctor and pharmacist if you are allergic to docetaxel or any other drugs.
- tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially aspirin, cyclosporine (Neoral, Sandimmune), erythromycin, ketoconazole (Nizoral), troleandomycin (TAO), and vitamins.

- tell your doctor if you have or have ever had liver or kidney disease.
- you should know that docetaxel may interfere with the normal menstrual cycle (period) in women and may stop sperm production in men. However, you should not assume that you cannot get pregnant or that you cannot get someone else pregnant. Women who are pregnant or breast-feeding should tell their doctors before they begin taking this drug. You should not plan to have children while receiving chemotherapy or for a while after treatments. (Talk to your doctor for further details.) Use a reliable method of birth control to prevent pregnancy. Docetaxel may harm the fetus.
- do not have any vaccinations (e.g., measles or flu shots) without talking to your doctor.

Side effects

Side effects from docetaxel are common and include:

- thinned or brittle hair
- diarrhea
- loss of appetite
- nausea
- vomiting

Tell your doctor if either of these symptoms is severe or lasts for several hours:

- mouth blistering
- fatigue

If you experience any of the following symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- unusual bruising or bleeding
- severe vomiting
- chills
- cough
- sore throat
- muscle aches, bone pain, and other flu-like symptoms
- difficulty swallowing
- change in normal bowel habits for more than 2 days
- swelling of the feet, increases in waistline size, weight gain, or overall puffiness

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Last Revised - 04/01/2003

Chemical: Bronopol go

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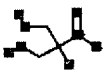
Enter a chemical name, CAS Number, or molecular formula. Use * for partial names (i.e. chloro*)

Synonyms: Bronopol, 1,3-Propanediol, 2-bromo-2-nitro-, Bronocot, Onyxide 500, 2-Bromo-2-nitro-1,3-propanediol, 2-Bromo-2-nitropropane-1,3-diol, Bronosol, 2-Nitro-2-bromo-1,3-propanediol, 2-Bromo-2-nitropropan-1,3-diol, beta-Bromo-beta-nitrotrimethyleneglycol, Bronopolu, Bronotak, 2-Bromo-1-nitro-1,3-propanediol, Bioban BNPD-40, Bronidiol, Bronopol-boots, Broponol, Canguard 409, Lexgard bronopol, Myacide AS plus, Myacide S-1, S-2, NIST52-51-7, NISTC52517



click for details

Search for: Bronopol	
IUPAC Name	2-bromo-2-nitro-propane-1,3-diol
CAS Number	52-51-7
Chemical Formula	C3H6BrNO4

Search web sites for Bronopol

Featured Suppliers and resources for *Bronopol* (Ads) List your site here

Linwood Chemical

Linwood chemical sells high quality dimethyl sulfoxide in ISO tank containers and drums from a dedicated ISO9001:2000 certified DMSO plant at reasonable prices. Linwood sources chemicals that are not readily available.
URL: http://linwoodchem.com/ [Translate]

Moto Chemistry Int'l Ltd. Manufacturer China

One of the most responsive specialty chemicals exporter & manufacturer in China. A leading supplier of pharmaceutical, biochemicals, dyestuff and agrochemical intermediates, ore chemicals and pigments.
URL: http://www.motochem.com/ in English [Translate]

CCS CHEM Industry service China

Many reliable primary suppliers are available. CHINA CHEM SERVICE acts as a convenient and efficient assistant to help you do chem BIZ with china including soucing, promoting, consulating, inspecting, sampling...
URL: http://www.cnchemservice.com/ in English [Translate]

Bohong Chemical International Co., Ltd. Industry service China

Based on long-term cooperation with many leading pharmaceutical manufacturers in China , we are prepared to execute customers highly specialized synthesis, the company devotes itself to the international trade of pharmaceuticals, chemical material and intermediate. Email: info@bhchem.com
URL: http://www.bhchem.com/ in English [Translate]

Find additional information about *Bronopol* at:

Chemical properties, names and structures

PubChem
NIST WebBook
ChemIDplus
MatWeb

ChemExper
NCI Database
SDBS
Merck ChemDat

Safety and toxicology data

ToxNet
ChemFate
Vermont SIRI
Cornell University
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Chemistry dictionary

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Literature

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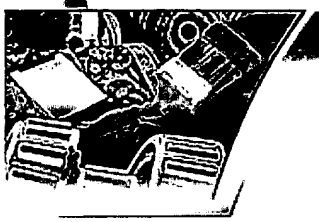

New Products

Cosmocil
Densil
Proxel
Reputex
Vanquish
Vantocil

Vantocil

Poly (hexamethylene biguanide) hydrochloride (PHMB), the active ingredient in our VANTOCIL antimic range is a fast-acting and broad spectrum bactericide with a wide formulation latitude. Consequently, b selection of appropriate co-formulants, a wide range of professional and domestic products can be form which meet the stringent demands of today's disinfection and hygiene industries.

VANTOCIL antimicrobials can be used to formulate a wide variety of applications including:

- Professional disinfection
  - Liquid hard surface disinfectants for surfaces and floors
  - Solid disinfection tablets (slow release and effervescent)
  - Water cooling towers
  - Tunnel pasteurisers
  - Room fogging
  - Disinfectants for medical devices and equipment
- Household products
  - Antimicrobial dish washing liquids
  - Antimicrobial fabric conditioners
- Sanitizing wet wipes (for surfaces and hands)
- Antimicrobial hand soaps

The primary performance benefits of PHMB include:

- Fast-acting and broad spectrum antimicrobial activity
- No cross-resistance with therapeutic antibiotics
- High level of retained biocidal activity in both soft and hard water conditions, and in the presence organic load (BSA, yeast extract, milk and sucrose)
- Stable and effective performance over a pH range of 1-11
- Low surface activity and consequently can be readily water rinsed from surfaces and provide ver foaming products for Clean-In-Place applications

Through its longstanding familiarity with PHMB, Arch Biocides is well placed to offer formulation guidan application advice in selecting the most appropriate co-formulants to ensure that your antimicrobial pro offer the performance you would expect.

Whatever the end-use, Arch Biocides will ensure that our VANTOCIL antimicrobials do the right job for

Request Literature